

SHORT TERM ORAL SWAB SYSTEM- hydrogen peroxide

Sage Products LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Short Term Oral Swab System

Drug Facts

<i>Active Ingredient</i>	<i>Purpose</i>
PEROX-A-MINT SOLUTION: 1.5% Hydrogen peroxide	Oral debriding agent

Use

Aids in the removal of secretions associated with sore mouth

Warnings

Do not use:

- For more than 7 days unless told to do so by a doctor.
- Avoid Swallowing.

Stop use and ask a doctor if:

- Sore mouth symptoms do not improve in 7 days.
- Swelling, rash or fever develops.
- Irritation, pain or redness persists or worsens.

Keep out of reach of children.

If more than used for debriding is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

Perox-A-Mint

- Use up to 4 times daily or as directed by a dentist or doctor.
- Adults and children 3 years and over: rinse mouth for approx. one minute with 1/2 Tbsp. Instruct to expectorate.
- Children under 12 years of age: supervise use.
- Children under 3 years of age: consult a dentist or doctor.

Oral Swab System

- Dip an Oral Swab into the Perox-A-Mint solution.
- Clean teeth and oral cavity for approximately one minute.
- Instruct to expectorate.
- Apply Mouth Moisturizer as needed.
- Discard after use.
- Swabs are intended for single oral use only.

- Use up to 4 times daily or as directed by a dentist or doctor.
- Children under 12 years of age should be supervised in the use of this product.
- Children under 3 years of age: consult a dentist or doctor.
- Use a bite block when performing oral care on patients with altered levels of consciousness or those who cannot comprehend commands.
- Ensure foam is intact after use. If not, remove any particles from oral cavity.

Inactive Ingredients

Water, menthol flavor, polysorbate 80, phosphoric acid, sodium saccharin, Blue 1 (CI42090), Yellow 6 (CI15985)

Questions


Call toll free 800-323-2220

MADE IN U.S.A.

NOT MADE WITH NATURAL RUBBER LATEX

Short Term Oral Swab System with Perox-A-Mint Solution

NPN 02242225



**Short-Term
Oral Swab System
with Perox-A-Mint® solution**

CONTENTS:
 20 Toothette Plus Oral Swabs with sodium bicarbonate
 1.5 fl. oz./44mL bottle Perox-A-Mint solution
 .5 oz./14g tube of Mouth Moisturizer

Pour la version française, consulter le feuillet ci-inclus

Drug Facts	
Active ingredient	Purpose
PEROX-A-MINT SOLUTION:	
1.5% Hydrogen peroxide	Oral debriding agent
Use	
Aids in the removal of debris and secretions.	
Warnings	
Stop use and ask a doctor if:	
<ul style="list-style-type: none"> • Sore mouth symptoms do not improve in 7 days. • Swelling, rash or fever develops. • Irritation, pain or redness persists or worsens. 	
Keep out of reach of children.	
If more than used for debriding is accidentally swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> • Dip an Oral Swab into the Perox-A-Mint solution. • Clean teeth and oral cavity for approximately 1 minute. • Instruct to expectorate. • Apply Mouth Moisturizer as needed. • Discard after use. 	
<ul style="list-style-type: none"> • Swabs are intended for single oral use only. • Use up to 4 times daily or as directed by a dentist or doctor. • Children under 12 years of age: supervise use. • Children under 3 years of age: consult a dentist or doctor. 	

- Children under 3 years of age: consult a dentist or doctor.
- Use a bite block when performing oral care on patients with altered levels of consciousness or those who cannot comprehend commands.
- Ensure foam is intact after use. If not, remove any particles from oral cavity.

Inactive ingredients

Water, menthol flavor (aroma), polysorbate 80, phosphoric acid, sodium saccharin, Blue 1 (CI 42090), Yellow 6 (CI 15985).

Questions or comments?

Call toll free 800-323-2220.

Sodium Bicarbonate ingredients

Water, sodium bicarbonate, sodium carboxymethyl cellulose, sodium lauryl sulfate, flavor (aroma), sodium saccharin, sodium benzoate.

Mouth Moisturizer ingredients*

Water, cocos nucifera (coconut) oil, xylitol, mentha viridis (spearmint) flavor (aroma), sodium carboxymethyl cellulose, tocopheryl acetate (vitamin E), mentha viridis (spearmint) leaf oil, carbomer, polysorbate 20, polysorbate 80, potassium sorbate, cetylpyridinium chloride.



3909 Three Oaks Road • Cary, Illinois 60013
www.sageproducts.com • 800-323-2220

Reorder # 6000



Made in U.S.A.

* Manufactured for Sage Products, Inc.
Covered under one or more of the following
U.S. Patent Numbers: D282,698

In Canada, imported by/Au Canada, importé par :
Cardinal Health Canada Inc. • Mississauga, ON L5T 1C2



LATEX FREE

R4561F

NPN 02242225



Oral Debriding Agent



R3674I

1.5 fl. oz./44 mL

Drug Facts

Active ingredient

Hydrogen Peroxide 1.5%.....Oral Debriding Agent

Use

Aids in the removal of secretions associated with sore mouth

Warnings

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Directions

- Use up to 4 times daily or as directed by a dentist or doctor.
- Adults and children 3 years and over: rinse mouth for approx. one minute with 1/2 Tbsp. Instruct to expectorate.
- Children under 12 years of age: supervise use.
- Children under 3 years of age: consult a dentist or doctor.

Inactive ingredients

Water, menthol flavor, polysorbate 80, phosphoric acid, sodium saccharin, Blue 1 (CI42090), Yellow 6 (CI15985)

Questions? Call toll free 800-323-2220

Sage Products, Inc.
3909 Three Oaks Road
Cary, IL 60013
800-323-2220
www.sageproducts.com

Reorder # 6065

Pour la version française,
consulter le feuillet ci-joint

In Canada, imported by:
Au Canada, importé par :
Cardinal Health Canada Inc.
Mississauga, ON L5T 1C2



SHORT TERM ORAL SWAB SYSTEM

hydrogen peroxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53462-201
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53462-201-30	1 in 1 KIT; Type 1: Convenience Kit of Co-Package	06/30/2007	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	44 mL
Part 2	1 TUBE	14 g
Part 3		1

Part 1 of 3

PEROX-A-MINT SOLUTION

hydrogen peroxide mouthwash

Product Information

Item Code (Source)	NDC:53462-075
Route of Administration	BUCCAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	15 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 KIT		
1	NDC:53462-075-30	44 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	05/21/1998	

Part 2 of 3

MOUTH MOISTURIZER

other oral hygiene products

Product Information

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	COCONUT OIL (UNII: Q9L0O73W7L)	
INGR	XYLITOL (UNII: VCQ006KQ1E)	
INGR	CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
INGR	POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
INGR	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
INGR	CETYL PYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
INGR	CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
INGR	SPEARMINT OIL (UNII: C3M81465G5)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 KIT		
1		14 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic			

Part 3 of 3

SODIUM BICARBONATE

other oral hygiene products

Product Information

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
INGR	CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
INGR	SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
INGR	SODIUM BENZOATE (UNII: OJ245FE5EU)	
INGR	WATER (UNII: 059QF0K00R)	
INGR	SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	06/30/2007	

Labeler - Sage Products LLC (054326178)

Registrant - Sage Products LLC (054326178)

Establishment

Name	Address	ID/FEI	Business Operations
Sage Products LLC		054326178	manufacture(53462-201, 53462-075)

Revised: 1/2019

Sage Products LLC